Presidential Commission for the Study of Bioethical Issues Meeting
Washington DC
August 1, 2012

International Perspectives on the Return of Individual Results and Incidental Findings

Bartha Maria Knoppers
Canada Research Chair in Law and Medicine
Director, Centre of Genomics and Policy
McGill University

Ma'n H. Zawati
Academic Associate
Centre of Genomics and Policy
McGill University

McGill

CGP
CENTRE OF GENOMICS AND POLICY
CENTRE DE GÉNOMIQUE ET POLITIQUES

Introduction

- « Should offer »
- « May offer »
- « Not return »

Wolf S. et. al., “Managing Incidental Findings and Research Results in Genomic Research Involving Biobanks and Archived Data Sets” (2012) 14:4 *Genetics in Medicine*, 361.

Introduction

- « Bin 1: Clinically actionable »
- « Bin 2: Clinically valid but not directly actionable »
  - Bin 2A: « Low risk, clinically valid results »
  - Bin 2B: « Medium risk results »
  - Bin 2C: « High risk results »
- « Bin 3: Unknown or no clinical significance »

Berg, JS, Khoury MJ and Evans JP., "Deploying whole genome sequencing in clinical practice and public health: Meeting the challenge one bin at a time", (2011) 13:6 *Genetics in Medicine*, 499.

Introduction

- « ICOB, or Informed Consent Oversight Board, is a group including ethicists, scientists, physicians, genetic counselors, and participant advocates who oversee both the research completed within TGP [The Gene Partnership] and the delivery of information back to patients. »
- « In particular, issues involving privacy, ethical use of participant information, appropriate standards of evidence for results delivery, thresholds of actionability around results delivery, and other complex issues are dealt with by the ICOB ».

- http://www.genepartnership.org/about-tgp/for-experts/

Introduction

- «Structural changes in research design, combined with governance changes in assessing impact, allow us to move beyond a binary construction of report/do not report and to create a structure in which the communicability of the message and the participants' preferences are variables in a function that affects results reporting. »

Kohane IS and Taylor PL, “Multidimensional Results Reporting to Participants in Genomic Studies: Getting It Right” (2010) 2:37 *Sci Transl Med*, 37cm19.

Introduction

Introduction

- Feedback at Enrollment
- Critical Values
- Return of General Research Results
- Return of Enriched Data to Biobanks
- Individual Return of Research Results

Canada

- The 2010 Canadian *Tri-Council Policy Statement* = obligation to return material incidental findings with significant welfare implications for the participant, whether health-related, psychological or social.

- Participants will be informed of a plan that will detail how they will receive such information.

From Disclosure to Facilitating Access

Estonia's *Human Genes Research Act* (2000):

- § 11. Other rights of gene donors

- (2) Gene donors have the right to access personally their data stored in the Gene Bank. Gene donors do not have the right to access their genealogies.

- (3) Gene donors shall not be charged for accessing their data stored in the Gene Bank.

Sweden

LifeGENE's Ethics Policy (2010):

- B.3 "[…] we will not in general provide participants with information (genetic or otherwise) about their own individual results derived from examination of the database or samples by research undertaken after enrolment […]
- However, there may be findings of new biomarkers implicating a very high risk of a preventable and serious disease. If such findings are made and corroborated, LifeGene may contact individual participants to communicate these findings, if LifeGene in agreement with relevant medical expertise finds this defensible."

Public Population Project in Genomics and Society

EJHG Open

European Journal of Human Genetics (2012), 1–3
© 2012 Macmillan Publishers Limited All rights reserved 1018-4813/12
www.nature.com/ejhg

POLICY

Population studies: return of research results and incidental findings Policy Statement

Bartha Maria Knoppers*[,1,2], Mylène Deschênes[3], Ma'n H Zawati[2] and Anne Marie Tassé[1]

Return of IRRs and IFs to participants: conditions and modalities

No return of IRRs and IFs. There may be population studies where the policy is not to return individual results or findings, and this was consented to by participants at recruitment. This remains a viable option where appropriate. Researchers accessing the study population and their local Ethics Review Committee should be made aware of this policy.

For population studies with a no-return policy or where participants did not consent at recruitment to the return of findings but have, nonetheless, consented to recontact for updates and for further questions or collection of samples, such a period can create an opportunity to explain and introduce a return of results and Ifs policy and accompanying procedures, if the population study so chooses and with ethics approval. Indeed, upon recontact, participants could be provided with an option to consent (or not) to receiving such results. Moving forward, population studies with a no return policy could consider adding such an option to their consent process at recruitment.

The Case of Pediatrics

What results?

No return

"Due to the experimental nature of the planned analyses, it will not be possible to inform you, or the father of your child, or your own doctors, of the results of any tests, including genetic tests, on your samples"

General/Aggregate

"You will have access to the general results of the study including analyses of samples and data, as we will keep you informed of publications arising from the research"

General/Aggregate + Individual

"If the study finds the gene and specific gene mutation associated with your genetic condition, the study doctor would offer to discuss these findings with you. … You will be provided with a summary of the results at the conclusion of this study"

Individual + incidental findings

"If we find information by chance that relates to another condition or conditions besides the one under study and it is life threatening or very serious and there is a treatment available, we will re-contact you unless you indicate you do not wish to be contacted"

Towards Best Practices for Health Research Involving Children and Adolescents

Emerging Issue	Best Practices
Return of research results	•The potential for research results and incidental findings disclosure must be described in the consent form •Individual research results and incidental findings should be communicated to the child and/or parents when they are actionable during childhood and either prevention or treatment is available (FORGE, Canada, 2011).

Quid: Same for incompetent adults in the absence of known wishes?

The Case of Pediatrics

EJHG Open

European Journal of Human Genetics (2012), 1–6
© 2012 Macmillan Publishers Limited All rights reserved 1018-4813/12
www.nature.com/ejhg

POLICY

Developing a policy for paediatric biobanks: principles for good practice

Kristien Hens*[,1], Carla E Van El[2], Pascal Borry[3], Anne Cambon-Thomsen[4,5], Martina C Cornel[2], Francesca Forzano[6], Anneke Lucassen[7], Christine Patch[8], Lisbeth Tranebjaerg[9], Eric Vermeulen[2], Elena Salvaterra[10], Aad Tibben[11,12] and Kris Dierickx[3] on behalf of the PPPC of the European Society of Human Genetics[13]

The participation of minors in biobank research can offer great benefits for science and health care. However, as minors are a vulnerable population they are also in need of adequate protective measures when they are enrolled in research. Research using biobanked biological
For example, small childr
and to give a documented
good practice related to t

8. The right of parents to receive or not to receive genetic information about their children is limited. In the rare case that information about a preventable or treatable early-onset disease is found, they should be notified regardless of their wishes providing the findings are subject to assessment of clinical validity and utility.

Conclusion

- Guidance (not regulation) implies the freedom to exercise professional judgement.
- Scientific validity, clinical utility and actionability remain the guideposts.
- Keep it simple and distinguish contexts, research goals and types of participation.
- i.e. Do not need elaborate criteria that cover all situations, but to delineate between different research contexts and provide simple criteria.
- To do otherwise will harm international collaboration and data-sharing.
- P.S. Keep the lawyers out of it! ☺